



IFW
Atty. Dkt. No. 034827-1501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Huang, et al.

Title: METHODS AND
COMPOSITIONS FOR THE
AMPLIFICATION OF
MUTATIONS IN THE
DIAGNOSIS OF CYSTIC
FIBROSIS

Appl. No.: 10/659,582

Filing Date: 09/09/2003

Examiner: Unknown

Art Unit: Unknown

<p align="center">CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below.</p> <p><u>DIANE GARCIA</u> (Printed Name)</p> <p><u>Diane Garcia</u> (Signature)</p> <p><u>6-11-04</u> (Date of Deposit)</p>

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003.

Accordingly, copies of these types of documents are not being supplied in connection with this

application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003*.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check

being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date June 10, 2004

FOLEY & LARDNER LLP
Customer Number: 30542
Telephone: (858) 847-6722
Facsimile: (858) 792-6773

By Barry S. Wilson

Barry S. Wilson
Attorney for Applicant
Registration No. 39,431



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/659,582
Filing Date	09/09/2003
First Named Inventor	Dong Hui Huang
Group Art Unit	1637
Examiner Name	Unknown
Attorney Docket Number	034827-1501

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	4,582,788		Erllich	04-15-1986	
	A2	4,683,194		Saiki et al.	07-28-1987	
	A3	4,683,202		Mullis	07-28-1987	
	A4	4,998,617		Ladd et al.	03-12-1991	
	A5	5,130,238		Malek et al.	07-14-1992	
	A6	5,169,766		Schuster et al.	12-08-1992	
	A7	5,846,710		Bajaj	12-08-1998	
	A8	5,885,775		Haff et al.	03-23-1999	
	A9	5,888,819		Goelet et al.	03-30-1999	
	A10	5,955,377		Maul et al.	09-21-1999	
	A11	5,981,178		Tsui et al.	11-09-1999	
	A12	6,011,588		Kim	01-04-2000	
	A13	6,288,220		Kambara et al.	09-11-2001	
	A14	6,355,429		Nygren et al.	03-12-2002	
	A15	6,403,320		Read et al.	06-11-2002	
	A16	6,406,844		Pirrung et al.	06-18-2002	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A17	WO	88/10315		Siska Diagnostics, Inc.	12-29-1988		
	A18	WO	89/06700		Genentech, Inc.	07-27-1989		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A19	Flanigan et al. "Rapid direct sequence analysis of the dystrophin gene." Am J Hum Genet. 2003 Apr;72(4):931-9.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/659,582
				Filing Date	09/09/2003
				First Named Inventor	Dong Hui Huang
				Group Art Unit	1637
				Examiner Name	Unknown
Sheet	2	of	2	Attorney Docket Number	034827-1501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A20	Hoogendoorn, B. et al., "Genotyping Single Nucleotide Polymorphism by Primer Extension and High Performance Liquid Chromatography " Human Genetics (1999) 104:89-93	
	A21	Jenison et al., Use of a thin film biosensor for rapid visual detection of PCR products in a multiplex format." Biosens Bioelectron. 16(9-12):757-63 (2001)	
	A22	Kwoh, D. et al., Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format." Proc. Natl. Acad. Sci. (U.S.A.) 86:1173 (1989)	
	A23	Landegren, U. et al. "A ligase-mediated gene detection technique." (1988) Science 241:1077-1080	
	A24	Mullis, K. et al., "Specific enzymatic amplification of DNA in Vitro: The Polymerase chain reaction." Cold Spring Harbor Symp. Quant. Biol. 51:263-273 (1986)	
	A25	Nickerson et al., "Automated DNA diagnostics using an ELISA-based oligonucleotide ligation assay." (1990) Proc. Natl. Acad. Sci. U.S.A. 87:8923-8927	
	A26	Piggee, C. et al. "Capillary Electrophoresis for the Detection of Known Point Mutations by Single-Nucleotide Primer Extension and Laser-Induced Fluorescence Detection" Journal of Chromatography A 781 (1997), p. 367-375	
	A27	Poddar "Symmetric vs asymmetric PCR and molecular beacon probe in the detection of a target gene of adenovirus." Molec. And Cell. Probes 14:25-32 (2000)	
	A28	Walker, G. T. et al., "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system." Proc. Natl. Acad. Sci. (U.S.A.) 89:392-396 (1992)	
	A29	Wall et al. "A 31-mutation assay for cystic fibrosis testing in the clinical molecular diagnostics laboratory." Human Mutation 5:333-338, 1995.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.